#### **REMARKS**

## I. Status of Claims.

This application has been reviewed in light of the Office Action dated October 25, 2006. Claims 4, 25 and 26 are presently pending. Claims 4, 25 and 26 have been amended in a manner that is believed to overcome rejections contained in the pending Office Action. The amendments to the claims were made to more specifically define Applicants' invention and not for reasons of prior art. No new matter or issues are believed to be introduced by these amendments. Support for the amendments can be found throughout the specification, the claims as originally filed and the drawings.

### II. Claim Objections.

The Examiner objected to claim 26 due to an informality and suggested an amendment to correct this informality. Applicant has amended claim 26 as suggested and thanks the Examiner for this suggested amendment.

### V. Claims 4, 25 and 26 rejected under 35 USC 112 first paragraph.

The Examiner rejected claims 4, 25 and 26 under 35 USC §112, first paragraph stating that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make an/or use the invention commensurate in scope with these claims. Applicant respectfully traverses this rejection.

A. Examiner's Rejection: The Examiner stated that the claims recite a method for obtaining an anti-tumor substance from colostrums, but one of skill in the art would not be able to practice the invention based on the disclosure in the claims and therefore, one of skill in the art would not be able to isolate an anti-tumor substance from colostrums. Applicant respectfully traverses this rejection.

Application Serial No. 10/501,438

Filed: July 13, 2004

A. Bertha

**B. Requirements of Written Description:** Applicant respectfully suggests that under the provision of 35 USC §112, first paragraph it is not required that Applicant disclose every last detail of the invention. The written description requirements generally require an Applicant to provide an enabling description of the invention sufficient for one of ordinary skill in the art.

The CCPA has stated that "[n]ot every last detail is to be described, else patent specification would turn into production specifications, which they were never intended to be." In re Gay, 309 F.2d 769, 135 USPQ 311, 316 (C.C.P.A. 1962). Applicant must merely provide sufficient detail as to allow a person skilled in the art the ability to practice the invention. This he has done.

Instructive guidance in determining the level of ordinary skill has been provided by the Federal Circuit as follows:

"The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art. The actual inventor's skill is not determinative. Factors that may be considered in determining level of skill include; type of problems encountered in art; prior art solutions to those problems. Rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." <u>Custom Accessories Inc. V. Jeffrey-Allan Indus.</u>, 807 F.2d 955, 1 U.S.P.Q. 2d 1196, 1201 (Fed. Cir. 1986).

It is settled law that a specification, drawn to one of ordinary skill in the art, need only describe enough information to allow one of ordinary skill in the art to make the invention work. Ex parte Naujoks, 17 U.S.P.Q.2d 1537, 1540 (PBAI 1989). Applicant respectfully notes that the first paragraph of Section 112 requires nothing more than objective enablement. This is achieved by the use of illustrative examples or by broad terminology. *In re* Marzocchi, 169 USPQ 367 (C.C.P.A. 1971). It is respectfully submitted that the method of isolation of the active substance is obtained from the colostrums by using a separation method that is of sufficient detail to enable o those of skill in the art, and having been cited are enabled. In particular,

Application Serial No. 10/501,438

Filed: July 13, 2004

A. Bertha

Applicant respectfully submits that the steps recited in claim 4 are those that are needed for isolation of the active substance. Accordingly, Applicants respectfully submit that the breadth of amended Claims 4 and 26 and claim 25 are clearly enabled by the instant specification. Claim language must be read in light of the specification as it would be interpreted by one of ordinary skill in the art. In re Moore, 58 CCPA 1042, 1046-1047, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (1971). Applicants respectfully submit that they have more than met the requirements of 35 USC 112 for claims 4, 25 and 26 and would therefore respectfully request that this rejection be withdrawn.

# VI. Rejection of claims 4, 11-13 and 15 rejected under 35 USC 112, second paragraph.

A. Examiner's rejection of claim 4: The Examiner further rejected claims 4 and 25 under 35 USC 112, second paragraph and stated, in regard to claim 4, that "[t]he claim is confusing because step c) recites that an upper layer and a medial layer (a crust) are separated from the rest." because it is not clear what the terms "the rest" means. In response the Examiner's rejection, Applicant has amended claim 4 and 25 to more clearly define Applicant's claimed invention. Applicant respectfully submits that with the amendments to the claims this rejection has been overcome.

Filed: July 13, 2004

A. Bertha

### CONCLUSION

Applicants respectfully request expeditious consideration and passage of the present application to issuance. The Examiner is invited and encouraged to telephone the undersigned if she believes such would facilitate prosecution of the present application.

Dated:

Respectfully submitted,

John C. Serio (Reg. No. 39,023)

Customer No. 21710

Attorney for Applicant(s)

Brown Rudnick Berlack Israels LLP

One Financial Center Boston, MA 02111

Tel: 617-856-8238

Fax: 617-856-8201

Email: ip@brownrudnick.com

# 1485147 v1 - SERIOJC - 025672/0005